Decision Memo for Prothrombin Time (PT) (Addition of two ICD-9-CM diagnosis codes) (CAG-00428N)

Decision Summary

CMS has determined that two ICD-9-CM diagnosis codes: 786.50, Chest pain, unspecified and 786.51, Precordial pain, flow from the existing narrative for conditions for which a prothrombin time (PT) test is reasonable and necessary. Consequently, CMS will add these two ICD-9-CM diagnosis codes to the list of "ICD-9-CM Codes Covered by the Medicare Program" for the national coverage determination (NCD) for PT testing, as stated in Section 190.17 of the NCD Manual.

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Decision Memo

TO: Administrative File: CAG-00428N
Prothrombin Time (PT) (Addition of two ICD-9-CM diagnosis codes: 786.50 Chest pain, unspecified and 786.51, Precordial pain)

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SUBJECT: Prothrombin Time (PT) (NCD Section 190.17)
Addition of Medicare coverage for two ICD-9-CM diagnosis codes: 786.50 Chest pain, unspecified and 786.51, Precordial pain

DATE: July 21, 2011

I. Decision

CMS has determined that two ICD-9-CM diagnosis codes: 786.50, Chest pain, unspecified and 786.51, Precordial pain, flow from the existing narrative for conditions for which a prothrombin time (PT) test is reasonable and necessary. Consequently, CMS will add these two ICD-9-CM diagnosis codes to the list of "ICD-9-CM Codes Covered by the Medicare Program" for the national coverage determination (NCD) for PT testing, as stated in Section 190.17 of the NCD Manual.

II. Background

The PT test is an in-vitro laboratory test used to assess the extrinsic or tissue factor dependent pathway. The test also evaluates the common coagulation pathway involving all the reactions that occur after the activation of factor X. Extrinsic pathway factors are produced in the liver and their production is dependent on adequate vitamin K activity. Deficiencies of coagulation factors may be related to decreased production or increased consumption. A PT test may be used to;

- assess patients taking warfarin; or
- assess patients with signs or symptoms of abnormal bleeding or thrombosis; or
- evaluate patients with a history of a condition known to be associated with the risk of bleeding or thrombosis that is related to the extrinsic coagulation pathway; or
- assess the risk of hemorrhage or thrombosis in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis.

III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled “ICD-9-CM Codes Covered by Medicare Program” and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled “ICD-9-CM Codes Denied” and lists diagnosis codes that are never covered by Medicare. The third list is entitled “ICD-9-CM Codes that Do Not Support Medical Necessity” and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary.

Also, the negotiating committee developed a list of “descriptors” for each of the 23 laboratory NCDs, which listed the CPT or other Health Care Procedure Coding System (HCPCS) codes for which the particular NCD applied. These codes described the procedures or services that a physician or other provider may deliver to a patient under the auspices of our NCD and flow from the narrative descriptions of the test indicated in the NCD. The CPT is developed and copyrighted by the American Medical Association.

IV. Timeline of Recent Activities

On January 21, 2011, CMS received an external request to add ICD-9-CM diagnosis code 786.50, Chest pain, unspecified to the list of diagnosis codes covered by Medicare for the PT testing NCD, from the Clinical Laboratory Management Association (CLMA), submitted by their president, C. Anne Pontius. Dr. Pontius’ letter suggested that the addition of this code is consistent with the narrative of indications in Section 190.17 of the NCD Manual. In addition, the addition of this code for coverage under 190.17 would bring that NCD policy into conformity with the list of codes approved for 190.16, partial thromboplastin time (PTT), in which the code 786.50 is included.

During the internal review at CMS, we noticed that the related code 786.51, Precordial pain, also seemed to flow from the narrative of 190.17, in particular a portion of the ‘Indications’ section of the policy that indicates a PT test might be useful in evaluating a patient with thrombosis such as a myocardial infarction.

We posted a tracking sheet to the Internet at: (http://www.cms.gov/medicare-coverage-database/details/cal-tracking-sheet.aspx?CALId=254) and solicited public comments for 30 days on the appropriateness of that proposal to add codes 786.50 and 786.51 to the PT NCD. No comments were received during the comment period.

V. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

On February 25, 2005, we announced in a final notice in the Federal Register (70 FR 9355) that we would maintain the accuracy of the coding lists without substantive changes to the narrative policy through an abbreviated process. We call this abbreviated process the Coding Analysis for Laboratories (CAL) process.

VI. CMS Analysis

The NCD includes the narrative Indications and Limitations below. We consider here whether prothrombin testing for chest pain flows from this narrative.

Indications

- A PT may be used to assess patients taking warfarin. The prothrombin time is generally not useful in monitoring patients receiving heparin who are not taking warfarin.
- A PT may be used to assess patients with signs or symptoms of abnormal bleeding or thrombosis. For example: swollen extremity with or without prior trauma; unexplained bruising; abnormal bleeding, hemorrhage or hematoma; petechiae or other signs of thrombocytopenia that could be due to disseminated intravascular coagulation.

- A PT may be useful in evaluating patients who have a history of a condition known to be associated with the risk of bleeding or thrombosis that is related to the extrinsic coagulation pathway. Such abnormalities may be genetic or acquired. For example: dysfibrinogenemia; afibrinogenemia (complete); acute or chronic liver dysfunction or failure, including Wilson's disease and hemochromatosis; disseminated intravascular coagulation (DIC); congenital and acquired deficiencies of factors II, V, VII, X; vitamin K deficiency; lupus erythematosus; hypercoagulable state; paraproteinemia; lymphoma; amyloidosis; acute and chronic leukemias; plasma cell dyscrasia; HIV infection; malignant neoplasms; hemorrhagic fever; salicylate poisoning; obstructive jaundice; intestinal fistula; malabsorption syndrome; colitis; chronic diarrhea; presence of peripheral venous or arterial thrombosis or pulmonary emboli or myocardial infarction; patients with bleeding or clotting tendencies; organ transplantation; presence of circulating coagulation inhibitors.
- A PT may be used to assess the risk of hemorrhage or thrombosis in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis. For example: evaluation prior to invasive procedures or operations of patients with personal history of bleeding or a condition associated with coagulopathy prior to the use of thrombolytic medication.

Limitations

- When an ESRD patient is tested for PT, testing more frequently than weekly requires documentation of medical necessity, e.g., other than chronic renal failure or renal failure, unspecified.
- The need to repeat this test is determined by changes in the underlying medical condition and/or the dosing of warfarin. In a patient on stable warfarin therapy, it is ordinarily not necessary to repeat testing more than every two to three weeks. When testing is performed to evaluate a patient with signs or symptoms of abnormal bleeding or thrombosis and the initial test result is normal, it is ordinarily not necessary to repeat testing unless there is a change in the patient's medical status.
- Since the INR is a calculation, it will not be paid in addition to the PT when expressed in seconds, and is considered part of the conventional prothrombin time.
- Testing prior to any medical intervention associated with a risk of bleeding and thrombosis (other than thrombolytic therapy) will generally be considered medically necessary only where there are signs or symptoms of a bleeding or thrombotic abnormality or a personal history of bleeding, thrombosis or a condition associated with a coagulopathy. Hospital/clinic-specific policies, protocols, etc., in and of themselves, cannot alone justify coverage.

We note that ICD-9-CM diagnosis code 786.59, Chest pain, other, is a covered indication in the list, and the list does not specify the other related chest pain diagnoses. We note in addition (as did the requesting party) that 786.50 is included as a covered ICD-9-CM code under Section 190.16 for PTT testing. Furthermore, noting that precordial pain may be a clinical symptom of myocardial infarction, we determine that, for the same reason, the ICD-9-CM code 786.51, Precordial pain, flows from the existing NCD 'Indications' language.

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